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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/521,335 03/09/00 OPPMANN

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HM22/0703

EXAMINER

TURNER, S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

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# Office Action Summary

Application No.  
09/521,335

Applicant(s)  
Oppman et al

Examiner  
Sharon L. Turner, Ph.D.

Art Unit  
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 9-7-00
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-30 are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

Art Unit: 1647

### **DETAILED ACTION**

1. Claims 1-30 are pending.

#### **Improper Markush**

2. Prior to setting forth the restriction requirement, it is pointed out that applicants have presented instant claims in improper Markush format, see Ex parte Markush, 1925 C.D. 126, In re Weber, 198 USPQ 334 and MPEP 803.02 and 806.04. The claims are improperly set forth as the genus claims encompassing multiple soluble complexes, recombinant polypeptides, methods, binding compounds, kits, nucleic acids and cells as identified in claims 1-30, fails to share the characteristics of a genus, i.e., a common utility and a substantial structural feature essential to the disclosed utility. Alternatively, the claims define multiple structurally distinct compounds capable of different use, with different modes of operation, different function and different effects. A reference against one of the claimed components or methods would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims define inventions which are not proper species.

#### ***Election/Restriction***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9 and 10(c) drawn respectively to polypeptide compositions and kit, classified for example in class 530, subclasses 300 and 350.

Art Unit: 1647

- II. Claim 10(a) drawn to a method of making an antibody, classified in class 435, subclass 69.3.
- III. Claim 10(b) drawn to a method of screening (immunoselecting antibodies), classified for example in class 436, subclass 518.
- IV. Claims 11-14 drawn to an antibody binding compound, classified for example in class 530, subclass 387.1.
- V. Claims 15-16 drawn to a method of producing an antigen antibody complex, classified for example in class 530, subclass 412.
- VI. Claims 17-20 and 22(b-c) drawn to nucleic acid, vector and host cell, classified for example in class 536, subclass 23.1.
- VIII. Claim 21 drawn to a kit comprising a nucleic acid and polypeptide, classified for example in class 436, subclass 536.
- IX. Claim 22(a) drawn to a method of making a duplex nucleic acid, classified for example in class 536, subclass 24.5.
- X. Claims 23-25 drawn to isolated nucleic acids classified for example in class 536, subclass 24.33.
- XI. Claim 26 drawn to a method of modulating physiology of a cell, classified for example in class 424, subclass 178.1.
- XII. Claim 27-28 drawn to a method of producing a complex, classified for example in class 435, subclass 320.1.

Art Unit: 1647

XIII. Claims 29-30 drawn to a method of screening for a receptor, classified for example in class 435, subclass 6.

4. The inventions are distinct, each from the other because of the following reasons:

5. Inventions I, IV, VI, VIII and X are related as products. The products are distinct each from the other as the products are comprised of divergent structure, effects and function, for example nucleic acids, peptides and antibodies.

6. Inventions II-III, V, VII, IX and XI-XII are related as processes. The processes are distinct each from the other as the processes differ in reagents, steps, functions and effects.

7. Inventions I, IV, VI, VIII, X and II-III, V, VII, IX and XI-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the nucleic acids, peptides and antibodies can be practiced with alternative nucleic acids, peptides and antibody products as evidenced by applicants claims and the products as claimed can be used alternatively in method of making antibodies, screening for compounds, of detecting compositions and for example as different methods of treatment as evidenced by applicants claims.

Art Unit: 1647

8. Furthermore, in addition to the election of one of the above XIII groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiment to which the claims will be restricted in accordance with the elected group:

- A) A single designated nucleic acid composition
- B) A single polypeptide composition/complex
- C) A single antibody (binding compound) composition/complex

9. The inventions are distinct, each from the other because of the following reasons:

10. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products indicated as A-C constitute patentably distinct inventions for the following reasons. Each of the polynucleotides, polypeptides and binding compounds (antibodies) has unique structural features which require a unique search of the prior art. The inventions indicated as A-C differ in structure and function as they are composed of divergent nucleic and amino acids and are differentially able to hybridize bind and mediate immune responses. A reference to one element would not constitute a reference to another. In addition, searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

Art Unit: 1647

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

12. Because these inventions are distinct for the reasons given above and the search required for any Group is not required for any other Group, restriction for examination purposes as indicated is proper.

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-XIII and a single molecular embodiment for each of designated groups A, B **and** C, even though the requirement is traversed. Applicant is advised that neither I-XIII nor A, B and C are species election requirements; rather each of I-XIII and A, B and C are restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups. It is noted that while one of A, B and C may not be applicable to one of I-XIII Applicant must elect one of each in order to be fully compliant.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

Art Unit: 1647

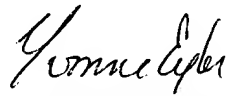
named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

16. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.  
July 2, 2001

  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
~~APPLICANT COPY~~